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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/394,020	09/10/1999	CARMEN V. PEPICELLI	HUIP-P01-032	3626

28120 7590 06/03/2003

ROPS & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

[REDACTED] EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/03/2003

38

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/394,020	PEPICELLI ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 March 2003.
 - 2a) This action is **FINAL**. 2b) This action is non-final.
 - 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- Disposition of Claims**
- 4) Claim(s) 1,2,4,5,22,24-28,34 and 35 is/are pending in the application.
 - 4a) Of the above claim(s) 22,34 and 35 is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) 1,2,4,5 and 24-28 is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| <input type="checkbox"/> Notice of References Cited (PTO-892) | <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | <input type="checkbox"/> Other: _____ |

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 24 March 2003 is acknowledged. Claims 1, 2, 4, 5, 22, 24-28, 34, and 35 are pending in this application. Claims 22, 34, and 35 are withdrawn from consideration as being drawn to the non-elected invention of modulation by FGF-10 therapeutics. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejection of claims 1-15, 24-33, and 35 under 35 U.S.C. 112, first paragraph, as lacking written description is withdrawn in response to Applicant's amendment.

3. The rejection of claims 1-5, 24-26, and 36 under 35 U.S.C. 103(a) as unpatentable over Fujitsa et al. and 22, 23, 27, and 28 as unpatentable over Fujita et al. in view of the '786 patent is withdrawn in response to Applicant's amendment requiring that the hedgehog antibodies inhibit expression of hedgehog. These claims are newly rejected under 35 U.S.C. 112, first paragraph, as adding new matter and as lacking enablement. Amendment of the claims to remove the new matter will result in reinstatement of the rejection of the claims under 35 U.S.C. 103(a), since *in vivo* treatment with an antibody, rendered obvious by Fujitsa et al., would inherently inhibit the action of hedgehog molecules produced by the surrounding cells.

New Grounds of Objection/Rejection

4. The amendment filed 24 March 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: the claims are now drawn to methods of

Art Unit: 1646

inhibiting expression using an antibody. Inhibition of expression by an antibody is not disclosed in the specification as originally filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. Claims 1, 2, 4, 5, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. As stated above, the specification as filed does not teach inhibition of expression using an antibody.

6. Claims 1, 2, 4, 5, and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As stated above, these claims now require inhibition of hedgehog expression by an antibody that interacts with hedgehog. Antibodies generally bind expressed protein; they do not affect the ability of a cell to make a given protein. Thus one of skill in the art would not predict, based on what is known in the art about antibody function, that inhibition of expression could be achieved with an antibody. The specification similarly provides no teachings to indicate that an antibody would inhibit expression. Thus the skilled artisan could not predictably achieve such inhibition and, without further guidance, it would require undue experimentation for the artisan to practice Applicant's invention as claimed.

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[yvonne.eyler@uspto.gov\]](mailto:[yvonne.eyler@uspto.gov]).

Art Unit: 1646

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
May 21, 2003

Yvonne Eyler
YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600